

REMARKS

Claims 1, 10, 12, 36 and 45 are amended. Claims 1-47 remain pending. Reconsideration is respectfully requested in view of the following remarks.

I. Claim Rejections Under 35 U.S.C. §112

The Examiner rejected claim 10 under 35 U.S.C. §112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” The Examiner asserts that “claim 10 recites the limitation ‘the logistics system’ in line 2. There is insufficient antecedent basis for this limitation in the claims.”

Applicants have amended claim 10 to correct the lack of antecedent basis. Therefore, Applicants request that the Examiner withdraw the rejection under § 112.

II. Claim Rejections Under 35 U.S.C. 102(b)

Lack of novelty under 35 U.S.C. § 102 (“anticipation”) requires that each and every element of the claimed invention be disclosed in a single prior art reference. Thus, a prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim. Under inherent anticipation, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. The Examiner rejected claim 45 under 35 U.S.C. §102(b) as being anticipated by Sloane (US Patent 5,619,991). The Examiner asserts that:

Claim 45 differs from claim 25 in that it is a World-Wide Web-based portal interface to a system for delivering a medical test to a patient and distributing the results of the test to a physician rather than a method for delivering a test unit to a patient and distributing results of the test. As per claim 45, Sloane teaches a World-Wide Web-based portal interface to a system for delivering a medical test to a patient and distributing the results of the test to a physician (Sloane; Figure 1, column 2, line 62 to column 3, line 28), comprising: a secure test ordering interface (Sloane; column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 28); and a secure test result retrieval interface (Sloane; column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 28).

Sloane is directed to a system of delivering medical services using electronic data communications. The system provides a software-based medical expert system that prompts a caller

for information necessary to render a diagnosis (*see, e.g.*, Fig. 1; Col. 3 lns 48-52; col. 4 lns. 3-9). The system can refer the patient out to a doctor or hospital or to receive physical tests (*see, e.g.*, Fig. 2, blocks 58, 65, 67; Col. 5, lns. 28-34). The process can also determine whether it is desirable to have certain physical tests performed either at a diagnostic center or local lab (*Id.*). Local lab can be equipped to perform a wide range of tests – blood, urine, sputum, etc. (*see, e.g.*, Col. 5, lns. 60-65).

Applicants' independent claim 45, as amended, is directed to a system for delivering a medical test device to a patient that includes a secure medical test device ordering interface. Sloane does not provide for delivering a medical test device to a patient. Therefore, Sloane does not teach each and every element of Applicants' claimed invention. Accordingly, Applicants request that the Examiner withdraw the rejection of claim 45 under 35 U.S.C. § 102(b) over Sloane.

III. Claim Rejections Under 35 U.S.C. 103(a)

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Failure to meet that burden requires overturning the obviousness rejection.

In particular, it should be noted that the use of hindsight by the Examiner is improper when setting forth an obviousness rejection. An inventor's explanation of how the invention works does not render obvious that which is otherwise unobvious

A. Claims 1, 3-44 and 46-47 over Sloane in view of McMenimen

The Examiner rejected claims 1, 3-44, and 46-47 under 35 U.S.C. §103(a) as being unpatentable over Sloane, U.S. Pat. No. 5,619,991, in view of McMenimen et al., U.S. Patent Publication 2002/0077850.

The Examiner asserts that:

[P]er claim 25, Sloane teaches a method for delivering a test unit to a patient and distributing results of the test, comprising: (a) receiving an order from a physician for distribution of a test to a patient via a computer coupled to a network (Sloane; column 1, line 62 to column 2, line 8); (b) verifying the authorization of the physician to place the order (Sloane; column 1, lines 60-61) and the patient to receive the order (Sloane; column 3, lines 54-55); (e) retrieving test results from the unit (Sloane; column 8, lines 47-56); and (f) distributing the test results (Sloane; column 1, line 62 to column 2, line 8).

Applicants respectfully note that Sloane does *not* teach “a method for delivering a test unit to a patient” as asserted by the Examiner. As discussed above, Sloane is directed to a system of delivering medical services using electronic data communications. Sloane’s system provides a software-based medical expert system that prompts a caller for information necessary to render a diagnosis. The system can *refer the patient out to a doctor or hospital or to receive physical tests*. The process can also determine whether it is desirable to have certain physical tests performed either at a diagnostic center or local lab. Local lab can be equipped to perform a wide range of tests – blood, urine, sputum, etc. *NO* test unit is delivered to a patient in the Sloane disclosure.

Further, the Examiner admits that Sloane fails to explicitly disclose: “(c) storing tracking information regarding a test unit shipped to the patient; and (d) shipping the test unit to the patient.” The Examiner asserts that the omitted features are well-known in the art asserting that:

McMenimen teaches (c) monitoring the “status of shipping and scheduled delivery” (reads on “storing tracking information regarding a test unit shipped”) to the patient (McMenimen; paragraph [0027]); and (d) shipping the test unit to the patient (McMenimen; paragraph [0028]) ... [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sloane to include these limitations, as taught by McMenimen, with the motivations of providing a system that has the following goals: build customized products to refill the medical institution's inventory order, automatic replenishment of stock in days, and the tracking of manufacturing and product information in order to effectively service customers.

The Examiner further asserts that “claim 1 differs from claim 25 in that it is a system for delivering an in-home test device to a patient rather than a method for delivering a test unit to a patient.” With respect to claim 36, the Examiner asserts that it “differs from claim 25 in that it is a system for delivering a medical test to a patient and distributing the results of the test to a physician rather than a method for delivering a test unit to a patient and distributing results of the test.”

Thus, the Examiner concludes “it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sloane to include these limitations, as taught by McMenimen, with the motivations of providing a system with ‘... a very quick turnaround time, e.g., a total of two days... [until]... delivery of the product...’ (McMenimen; paragraph [0026]).”

McMenimen is directed to a response manufacturing and inventory control system. The McMenimen disclosure teaches the application of build to order manufacturing and control systems, such as those used by Dell, for manufacturing implantable medical devices in response to a physician’s device request.

As the Examiner correctly concedes Sloane does not disclose a system including a shipping system coupled to the secure test ordering interface, as claimed by Applicants. While the McMenimen system may include a shipping system, it does not teach Applicants claimed invention because it does not provide systems adapted for: delivering an in-home test device to a patient (independent claim 1); delivering a home test unit to a patient (independent claim 12); shipping the test unit to the patient (independent claim 25); delivering a medical test device to the patient (independent claim 36); or delivering a medical test device to the patient (independent claim 45), as claimed by Applicants. Importantly, there is no suggestion in McMenimen that its teachings can or should be combined with Sloane. Even if McMenimen was combined with Sloane, the combination would not arrive at any of Applicants’ claimed systems.

Dependent claims 3-11 depend directly or indirectly from independent claim 1, and include the limitations thereof. Thus, for the foregoing reasons claims 3-11 are patentable under 35 U.S.C. § 103(a) over Sloane in view of McMenimen. Dependent claims 13-24 depend directly or indirectly from independent claim 12 and include the limitations thereof. Thus, for the foregoing reasons claims 13-24 are patentable under 35 U.S.C. § 103(a) over Sloane in view of McMenimen. Dependent claims 26-35 depend directly or indirectly from claim 25 and include the limitations thereof. Thus, for the foregoing reasons, claims 26-35 are patentable under 35 U.S.C. § 103(a) over Sloane in view of McMenimen. Dependent claims 37-44 depend directly or indirectly from claim 36 and include the limitations thereof. Thus, for the foregoing reasons, claims 37-44 are patentable under 35 U.S.C. § 103(a) over Sloane in view of McMenimen. Finally, dependent claims 46-47

depend directly or indirectly from claim 45 and include the limitations thereof. Thus, for the foregoing reasons, claims 46-47 are also patentable under 35 U.S.C. § 103(a) over Sloane in view of McMenimen.

For the foregoing reasons, Applicants request that the Examiner withdraw the rejection of claims 1, 3-44, and 46-47 under 35 U.S.C. §103(a) as being unpatentable over Sloane, U.S. Pat. No. 5,619,991, in view of McMenimen et al., U.S. Patent Publication 2002/0077850.

B. Claim 2 over Sloane in view of McMenimen, further in view of Welner

The Examiner rejected claim 2 under 35 U.S.C. §103(a) as being unpatentable over Sloane, in view of McMenimen et al. (US Publication 2002/0077850), as applied to claim 1 above, and further in view of Welner (US Patent 5,612,870). The Examiner asserts "as per claim 2, Sloane and McMenimen teach a system as analyzed and discussed in claim 1 above." The Examiner concedes that Sloane and McMenimen fail to explicitly disclose a system wherein the test ordering system comprises a call center. However, the Examiner asserts that the above features are well-known in the art, as evidenced by Welner because "Welner teaches a system wherein the test ordering system comprises a call center (Welner, column 1, lines 39-40, column 3 lines 21 -22)."

Dependent claim 2 depends from claim 1 and includes the limitations thereof. As discussed above with respect to the § 103 rejection of claim 1 over Sloane and McMenimen, neither reference establishes a method for delivering a test unit to a patient. Welner does not correct this deficiency. Therefore Applicants invention is not obvious over the prior art of record and the Examiner is requested to remove the rejection.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any additional fees that may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 13463-701.202).

Respectfully submitted,



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By: _____

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